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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,946	06/11/2007	Jens Egebjerg Nielsen	P69516US1	2115
136	7590	06/02/2011	EXAMINER	
JACOBSON HOLMAN PLLC			WILSON, LARRY ROSS	
400 SEVENTH STREET N.W.			ART UNIT	PAPER NUMBER
SUITE 600			3767	
WASHINGTON, DC 20004			MAIL DATE	
			06/02/2011	
			DELIVERY MODE	
			PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/589,946	NIELSEN ET AL.
	<b>Examiner</b> LARRY R. WILSON	Art Unit 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 March 2011.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32-42 is/are pending in the application.
  - 4a) Of the above claim(s) 42 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 August 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-878)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No./Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No./Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 32-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,755,173 to April A. Konopka et al. (Konopka).

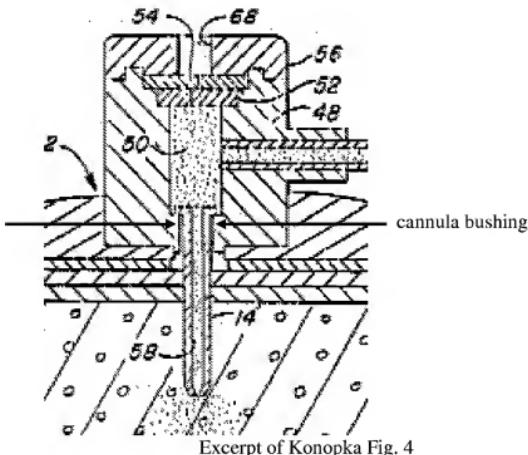
In regards to claim 32, Konopka discloses a septum housing for an infusion device, comprising a tubular element (Fig. 4, #48, 56) accommodating a septum (Fig. 4, #52, 54), the septum providing a fluid-tight seal toward an interior of the septum housing (col. 7, lines 62-68) and being pierceable by a needle (Fig. 2, #22), the septum being radially compressed by inner surfaces of the tubular element (Fig. 5B, #76; col. 8, lines 18-20, 32-34).

In regards to claims 33-36, Konopka discloses the septum housing according to claim 32, and further discloses:

Claim 33: at least one end of the tubular element provides a substantially partial enclosure over one surface of the septum (Fig. 4, #68 – aperture 68 exposes the septum and provides substantially partial enclosure);

Claim 34: one end of the tubular element is open and leaves the surface of the septum exposed (Fig. 4, #68);

Claim 35: the tubular element is a cannula bushing (Fig. 4 – no special definition was found in the specification, the plain meaning of bushing would be a "usually removable cylindrical lining for an opening used to limit the size of the opening, resist abrasion, or serve as a guide" Merriam-Webster <http://www.merriam-webster.com/dictionary/bushing?show=0&t=1306264971>, accessed 24 May 2011; the tubular element is a bushing that guides and retains the cannula for insertion into the patient's skin);



Excerpt of Konopka Fig. 4

Claim 36: the septum is fixed to inner surfaces of the septum housing by friction (col. 8, lines 32-34 – a component is sized larger than the holder to retain it inherently forms a friction fit).

In regards to claim 37, Konopka discloses an infusion device comprising a septum housing (Fig. 4, #48, 56) that includes a tubular element (Fig. 4, #48, 56) accommodating

a septum (Fig. 4, #52, 54), the septum providing a fluid-tight seal toward an interior of the septum housing (col. 7, lines 62-68) and being pierceable by a needle (Fig. 2, #22), the septum being radially compressed by inner surfaces of the tubular element (Fig. 5B, #76; col. 8, lines 18-20, 32-34), and a base element (Fig. 4, #46) that includes a mounting surface (Fig. 4, approximately at #12; col. 6, lines 20-22), a distal end of the septum housing that faces away from a surface on which the infusion device is mounted constituting a part of an outer distal surface of the infusion device (Fig. 4, #56 – has an outer surface that is in direct opposition to the surface 32 mounted to the skin of the patient and forms an outer surface of the infusion device).

In regards to claims 38-41, Konopka discloses the infusion device according to claim 37, and further discloses:

Claim 38: one end of the tubular element provides a substantially partial enclosure over one surface of the septum (Fig. 4, #68 – aperture 68 exposes the septum and provides substantially partial enclosure), the end of the tubular element constituting a distal end of the septum housing (Fig. 4, #68, 56 – the cap 56 part of the septum housing is at the distal end facing away from the skin of the patient, the aperture 68 is formed in the cap at the distal end of the housing);

Claim 39: the septum housing is fixed to the base element by welding (col. 9, lines 43-46);

Claim 40: the welding is ultrasonic welding (col. 9, lines 43-46);

Claim 41: the septum housing is fixed to the base element by a snap-lock (col. 9, lines 43-46).

***Response to Amendment***

3. The amendment to claims 32, 35, and 37 in the response filed on 21 March 2011 is acknowledged.

***Response to Arguments***

4. Applicant's arguments with respect to claims 32-41 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's amendments to independent claims 32 and 37 to define the fluid-tight seal of the septum and inner surface of the tubular element radially compressing the septum necessitated the new grounds of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 8:00 AM - 5:30 PM (EST), Every Other Friday 8:00 AM - 4:00 PM.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LARRY R WILSON/  
Examiner, Art Unit 3767

/Theodore J Stigell/  
Primary Examiner, Art Unit 3763